UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/020,393	02/09/98	SIMS	P OMRF-170

D/C

EXAMINER

HM12/0608

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ART UNIT	PAPER NUMBER
1644	10

DATE MAILED: 06/08/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 3/10/99

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-35 is/are pending in the application.
Of the above, claim(s) 1-9, 13-15, 18-35 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 10-12, 16-17 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-496/40517

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1644.

2. Applicant's election with traverse of Group II and the species antibodies as defined by Claims 10-12 and 16-17 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that while there are separate inventions, there are not 32 of them; that it is axiomatic that inventions or species are patentably distinct only if they are not obvious over each other and that the prosecution of multiple applications places an undue burden on research institutions. This is not found persuasive because of the inventions must be independent (see MPEP 802.01, 806.04, 808.01) or distinct as claimed (see MPEP 806.05-806.05(I))) for the reasons of record set forth in the Restriction Requirement (Paper No. 8).

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9, 13-15 and 18-35 have been withdrawn, as being drawn to the non-elected inventions and species.

The instant claims are drawn to methods of inhibiting C5-9 complex with antibodies that bind C9.

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Applicant is required to identify the nucleotide and amino acid sequences in the specification with SEQ. ID NOS.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

4. Claims 10-12 and 16-17 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite in the recitation of "Molecules structurally mimicking CD59 amino acid residues 42-58 when they are in a spatial orientation which inhibits formation of the hu C5b-9 complex when the compound is not hu CD59" because the characteristics of these "molecules", including as it reads on anti-C9 antibodies, as the elected invention is ambiguous and confusing. This language is vague and indefinite since it encompasses a myriad of different "molecules" and it is not apparent from the disclosure which particular "molecules" are being referred to. Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) that distinctly identifies the "molecules that structurally mimic CD59 ... " encompassed by the claimed invention. The recitation of "molecules that structurally mimic CD59 ... " fails to distinctly claim what that molecule is made up of. Therefore, there is insufficient information and guidance for the metes and bounds of the molecules that structurally mimic CD59 ... ".

With respect to the elected invention of anti-C9 antibodies; it is not clear that the skilled artisan would indicate that an anti-C9 antibodies that inhibits the formation of human C5b-9 complex acts as a mimic of CD59 rather than an agent/antibody that blocks receptor-ligand interactions. The claimed limitation of an anti-C9 as a mimic in this case appears to be confusing. Applicant is invited to amend the claims accordingly, particularly with respect to the elected invention.

There is insufficient direction or guidance provided to assist one skilled in the art in the selection of such "molecules that structurally mimic CD59 .... " commensurate in scope with the claimed methods, nor is there sufficient evidence provided that all such "molecules that structurally mimic CD59 ... " could be used in a practical manner either in vitro or in vivo to inhibit C5b-9 complex. The instant disclosure provides for certain C9-specific antibodies as well as certain CD59-derived constructs. Minor structural differences among structurally related compounds or compositions can result in substantially different pharmacological activities. Therefore, structurally unrelated compounds comprising antibodies, proteins, peptides, nucleic acids and small molecules would be expected to have greater differences in their activities, particularly when these diverse molecules are expected to have a particular three-dimensional structure that is suppose to mimic CD59. It would require undue experimentation to produce all such possible "molecules" without more explicit guidance from the disclosure. It would require undue experimentation to investigate all such "molecules". Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. It appears that undue experimentation would be required of one skilled in the art to practice the claimed "molecules" commensurate in scope with the claimed invention using the teaching of the specification.

The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter.

5. Claims 10-12 and 16-17 are objected to because "hu" should be spelled out for clarity.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 10-12 and 16-17 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Sims et al. (U.S. Patent No. 5,550,108) (see entire document). Sims et al. Teaches the use of anti-C9 antibodies to inhibit C5b-9 complex. This reference differs from the instant methods by not disclosing CD59 per se, however it appears that antibodies that bind C9 which inhibit C5b-9 complex formation would have the inherent properties of the claimed methods. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods of using C9-specific antibodies to inhibit C5b-9 complex formation and complement-mediated inflammation. The burden is on the applicant to establish a patentable distinction between the claimed and referenced methods. Also, see.Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

9. Claims 10-12 and 6-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Sims et al. (U.S. Patent No. 5,550,108) in view of Chang et al. (J. Biol. Chem., 1994; 1449).

Sims et al. teaches the use of anti-C9 antibodies to inhibit C5b-9 complex, which can be used to inhibit complement-mediated inflammatory responses (see entire document). This reference differs from the instant methods by not disclosing CD59 per se, however it appears that antibodies that bind C9 which inhibit C5b-9 complex formation would have the inherent properties of the claimed methods.

Chang et al. teaches the nature of the interaction between C9 and CD59, including identifying the peptide domain of human C9 that is bound by CD59 (e.g. residues 359-411) and the importance of these interactions in complement-mediated activities (see entire document).

One of ordinary skill in the art at the time the invention was made would have been motivated to select for anti-C9 antibodies that inhibit C5b-9 complex formation in modulating complement-mediated inflammatory responses, including selecting for those anti-C9 antibodies that inhibit CD59-mediated interactions with C9 and the complement cascade. The residues of 359-384 of C9 would have been targeted given the screening for inhibiting C5b-9 complex formation and the role of these residues in CD59 binding, as taught by the references. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Group 1640
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June 7, 1999

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